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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,554	04/07/2005	Hiroyuki Sato	10936-86	8861
24256	7590	11/26/2007	EXAMINER	
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			MESH, GENNADIIY	
		ART UNIT		PAPER NUMBER
		1796		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/530,554	SATO ET AL.
	Examiner Gennadiy Mesh	Art Unit 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 October 2007.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4 and 6-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4 and 6-22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2007 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1,4, 6 and 10 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and in further view of Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94( hereafter HTP).

Regarding Claim 1 and 4 Shinoda discloses preparation ( see abstract) process of polyester with desirable MW(molecular weight) or melt viscosity( note, that melt viscosity of a **resulting aliphatic polyester** polymer is proportional function of the MW of the polyester ) from cyclic esters or their mixtures ( see lines 5 –15,column 1), wherein impurities as water and hydroxycarboxylic acids ( including oligomers) are accurately controlled ( thus proton concentration also controlled) with total amount less

than 100 ppm (see abstract, lines 40 – 68, column 2, line 5-7, column 3 and line 50, column 6) in order to produce polyester with desirable MW ( see lines 1-5, column 3).

Shinoda is silent about addition of water to polymerization system. However, addition of water in order to start ring-opening polymerization process is known in the art. For example, Howelton teach addition of water ( as polymerization initiator) in ring – opening polymerization( see line 20, column1).

Therefore, it would have been obvious to one of ordinary of skill in the art to use purified cyclic ester in order to obtain polyester with desirable MW (or melt viscosity) per teaching of Shinoda and add water to polymerization system in order to start or/and increase rate of polymerization as it shown by Howelton.

Shinoda in view of Howelton silent about conducting polymerization in closed volume – particularly inside closed tubes as it claimed by Applicant in Claim 1 and 11.

However, ring –opening polymerization process can be conduct in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process – no volatile byproducts are generated during polymerization process as it disclosed in HTP (pages 90-94).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton inside closed tubes ( as a simple polymerization reactors), as it claimed by Applicant, due to significant reduction of overall cost of production equipment due to simplicity of this type of reactors( tube).

Regarding Claim 12 Shinoda in view of Howelton silent about conducting polymerization in solid state after initial polymer was produced.

However, solid-state polymerization of polyesters in order to increase MW ( or melt viscosity) of the polymer is well known in the art and would be obvious extension of polymerization process as it disclosed in HTP( pages 80 –82).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton with following step of solid-state polymerization as it thought in HTP in order to increase MW of the final polymer.

Subject mater claimed by Applicant in Claims 13 – 16 was discussed above. Also see Shinoda: lines 5-17,column 1; lines 20 – 25,column 6 and Example 6, wherein copolymer of glycolide and other cyclic monomer is disclosed.

Regarding Claims 17 – 20 : Shinoda in view of Howelton discloses substantially same process capable of producing substantially same product as a polyester with same MW. It will be reasonable to believe that other properties as viscosity and Yellowness index will be also substantially same. Burden shits to Applicant provide factual results to the contrary.

2. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and HTP( hereafter HTP), as applied to claims 1,4,6 and 13 –20 above, and further in view of Early (US 6,437,565).

Regarding Claims 7 – 9: as it shown by Shinoda in view of Howelton and HTP impurities and proton concentration –(see above) are controlled factor in preparation process of the polyester with desirable MW ( or melt viscosity as it explained above – see paragraph 1), but silent about regressional correlation between proton concentration and specific physical properties govern by MW of the polymer.

However, regressional analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressional analysis ( see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressional analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton.

#### ***Response to Arguments***

3. Applicant's arguments filed October 23,2007 have been fully considered but they are not persuasive.
- 3.1. Regarding Applicant's arguments related to Claims 1,3-6 and 13 - 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918):

i) As it was stated in original rejection- Shinoda disclosed process wherein polymer with desirable characteristics is obtained by controlling impurities that contribute to overall proton concentration:

"The cyclic ester compound used in the invention is preferably dehydrated as much as possible before subjecting to the polymerization reaction. When the moisture content is high, molecular weight control of polyester is liable to be difficult. Consequently, moisture content of the cyclic ester compound is preferably 0.5% by weight or less, more preferably 1,000 ppm by weight or less. **In order to accurately control the molecular weight of polyester having a molecular weight of 100,000 or more in particular, moisture content of the cyclic ester compound is preferably 100 ppm by weight or less.**" (**Column 6, lines 39-50**) – thus, first Applicant's argument is not persuasive.

ii) Shinoda as a Primary reference does not need teach all elements of Applicant's Claims 1,3-6and 13-20. Adding water to the polymerization system was taught by Secondary reference as Howelton. Thus, Applicants second argument is not persuasive.

iii) Regarding amount of volatile matter in the melt : it is clear that all additional compounds, including moisture ( water or /and monomer ) can act as a plasticizer and affect melt viscosity of the **melt** ,comprising melted polyester. However, melt viscosity of the **pure polyester** is a function of MW of the polyester. As it was point out above,

language of Claim 1 directed to “**resulting aliphatic polyester**”— arguments directed to amount of volatile matter is irrelevant to claimed subject matter of Claims 1 and 3 – 20.

iii) Regarding Applicant’s argument that Shinoda use alcohol as a Molecular weight regulator – note, that language of Applicant’s claims is open to any additional compounds and is not specifically exclude lauryl alcohol from claimed subject matter.

3.2. Regarding Applicant’s arguments related to Claims 7-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) as applied to claims 1-6 and 13 – 20 above, and further in view of Early (US 6,437,565).

As it was discussed in original rejection, Shinoda in view of Howelton teach that impurities and proton concentration (see above) are controlled factor in preparation process of the polyester with desirable MW, but silent about regressive correlation between proton concentration and specific physical properties govern by MW of the polymer. Note, that regressive analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressive analysis ( see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressive analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton.

3.3. Regarding Applicant's Arguments related to Claims 10-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) as applied to claims 1-6 and 13 –20 above, and further in view of Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94 ( hereafter – HTP):

i). Regarding Applicant's arguments ( see page 17 of Remarks) conducting ring-opening polymerization in closed volume - HTP teach that ring-opening polymerization process can be conduct in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process – no volatile byproducts are generated during polymerization process – it is obvious, **based on this teaching**, to conduct polymerization in closed volume.

ii) Note, when ring-opening polymerization is completed- all cyclic structures are opened – than low molecular weight polymers can be subjected to SSP (Solid state polymerization) as it routinely done in the art.

***Conclusion***

**THIS ACTION IS NOT MADE FINAL.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gennadiy Mesh whose telephone number is (571) 272 2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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